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**Re-configuring the concept of vulnerability: Inclusion of  
refugees in biomedical research**

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## Introduction

Vulnerable populations in biomedical research have attracted attention in research ethics since the creation of the Nurnberg code in 1947. Research guidelines establish ethical principles in order to protect vulnerable individuals from exploitation in biomedical studies. Vulnerable groups may include women, children, the mentally disabled, racial minorities, or refugees. In this thesis, I will focus in particular on refugees. The uniqueness of refugees can be defined through their contextuality. Particular, refugees are not just vulnerable individuals who live in the same social, cultural and legal contexts with researchers, but they move from the context of their home country to another context of the host country, thus bringing one context within another. This contextuality may contribute to additional complexities for the inclusion of refugees to a biomedical study.

The term “refugee” will be applied in this thesis in accordance with the 1967 Convention and Protocol relating to the Status of Refugees. It applies to people who are “unable or unwilling to return to their country of origin owing to a well-founded fear of being persecuted for reasons of race, religion, nationality, membership of a particular social group, or political opinion” (United Nations High Commissioner for Refugees, 1967). I will explore the consequences that refugees may experience due to their entitlement as vulnerable individuals and their particular protection in biomedical studies.

Biomedical research can be determined as “the broad area of science that involves the investigation of the biological process and the causes of disease through careful experimentation, observation, laboratory work, analysis, and testing” (California Biomedical Research Association, 2016). Vulnerability in the context of biomedical research is often associated with the capacity of potential research subjects to provide voluntary informed consent. Alternatively, vulnerability can be defined as the jeopardized ability of autonomous decision-making, where autonomy is broadly understood as personal independence (O’Neill, 2002). Although, this thesis is focusing on the concept of vulnerability in its application to refugees as potential participants of biomedical studies, some of the general arguments about the concept of vulnerability in biomedical research can be relevant for other groups such as women, children or prisoners.

Biomedical research involving presumably vulnerable refugees, on the one hand, has a potential to advocate for refugees’ health issues, as well as for their right to

be considered in health policy (Perry, 2011). On the other hand, however, such studies require particular attention, as they have a potential to harm people that are already worse off. In addition, refugees have a questionable capacity for autonomous reasoning, due to their dependence on others' mercy. Therefore, biomedical studies may exploit refugees' vulnerability for their own means.

The concept of the vulnerability of refugees as jeopardized ability of autonomous reasoning is the focus of the current thesis. This concept will be analyzed from the perspective of the enduring ethical tension between clinical care and public health ethics, where the former is focused on individuals and treatments, and the latter deals with populations and long-term public health goals (Petrini, 2012). There are some critical debates regarding the difficulty of the association of research and care, and also concerning the important question of trust. However, in this thesis I will make an attempt to combine principles of clinical care and public health ethics. Although, biomedical studies are usually focused on the benefits of future patients and populations, when vulnerable individuals involved in a biomedical research, the lack of personal benefits for these participants can be recognized as the exploitation of their vulnerability. I will argue that the combination of clinical and public health rationales will help to soften the vulnerable position of refugees and help to improve both their personal health status and public health policies.

However, it must be acknowledged that the combination of personal and public health benefits within one study increases the risk of a therapeutic misconception of research as care. The possibility of this misconception is particularly high in refugee research, as most people in refugee camps have never participated in any studies, or may have never heard about such studies. To overcome this complexity, I will propose a methodological solution that incorporates a participatory approach into the process of biomedical studies. However, the combination of research and care that often leads to the union of roles of researchers and physicians constitutes a serious risk of exploitation of vulnerable refugees and thus requires a critical position of refugees towards the research and researchers. I will suggest a reevaluation of the position of refugees as silent participants in research to active players in the development of research processes. This would, however, require the re-conceptualization of the presumed vulnerability of refugee populations.

For the purpose of this thesis, I will focus only on refugees living in asylum centers in Western Europe, as I have based my arguments on empirical materials from this part of the world. To illustrate the arguments, I will refer to a study where I

participated in and conducted a series of interviews with microbiologists, public health doctors, nurses and Syrian refugees. This research began in June 2016 and is focused on studying the level of antimicrobial resistance (AMR) among Syrian refugees in Maastricht, the Netherlands. AMR is an evolutionary development process of microorganisms that evolve the ability to withstand antimicrobial drugs, thus making the treatment of infections ineffective and raising the risk of spreading resistant microorganisms to other people. It is important to note that AMR screening for public health purposes is usually conducted among healthy individuals in order to understand the overall picture of the ecological community of pathogenic and non-pathogenic microorganisms. Such screenings do not provide any individual results for participants, as these results can neither benefit nor harm them. My role in this study was to analyze the attitudes and values that different participants in the research had towards AMR. This understanding of different values helped us to develop an ethically appropriate framework to work with sensitive questions related to the antimicrobial resistance of refugees.

The thesis consists of five chapters. The first chapter gives an overview of the concept of autonomy and the way this concept has been constructed in medical ethics. I will show how the concept of vulnerability, which indicates certain risks for autonomy, has been shaped in research ethics. The second chapter is devoted to an in-depth analysis of the concept of vulnerability in biomedical research, its rationale, and its limitations. In this chapter, the focus will be on the Belmont Report as one of the most important documents that defines an ethical framework for biomedical studies and gives an explicit definition of vulnerability. The chapter looks through the motivation and reasoning for establishing the concept of vulnerability and provides a critical analysis of its limitations. In the third chapter, I will discuss the concept of vulnerability and its re-definition by three groups of scholars: Hurst (2008), Lange et al. (2013), and Luna (2009). These authors propose context-sensitive understandings of vulnerability that expand beyond its definition in the Belmont Report. I will critically synthesize the three approaches of these authors and emphasize the necessity of looking at the design of biomedical research itself. In this chapter, I will argue for the benefits of participatory methodology. The fourth chapter will give a detailed overview of participatory methodology and of its adaptation in anthropology and learning health system. In the fifth and conclusive chapter, I will analyze what possibilities and limitations participatory methodology

can bring to biomedical research involving refugees and propose my own design for conducting such studies.

## **Chapter 1. Respect for autonomy: foundations of the principle**

Before examining the concept of vulnerability in biomedical research, we first have to understand the origin of this concept. As was mentioned in the introduction, vulnerability in biomedical research is often associated with the ability of potential research participants to provide voluntary informed consent (to understand information, to judge it according to one's values, and to express voluntary consent). This ability is rooted in persons' capacity to exercise their autonomy and to make autonomous decisions. Therefore, vulnerability in biomedical research can be defined as certain risks associated with the expression of such autonomous decisions, or as a jeopardized ability to exercise one's autonomy.

The word autonomy refers to the Greek "autos" and "nomos" that was primarily understood as self-rule or self-law and that was associated with the governance of an autonomous state. Therefore, autonomous individuals are those who act according to their own laws and rules. Vulnerable people, by contrast, are those who feel threatened if they act according to their own rules and desires, and whose autonomy is therefore influenced by others. In medical ethics, respect for the autonomous choices of persons is recognized as one of the main principles in conducting biomedical studies involving human subjects. This principle aligns with the principles of beneficence, non-maleficence, and justice, which were introduced and thoroughly analyzed by scholars Beauchamp & Childress in their famous book "Principles of Biomedical Ethics" (2009). Respect for autonomy, according to Beauchamp & Childress (2009: 103), encompasses respect for autonomous agents and acknowledgment of "their right to hold views, to make choices, and to take actions based on their personal values and beliefs".

Beauchamp & Childress (2009) introduced four principles of biomedical ethics, including the respect for autonomy, which may be seen as a classic ethical framework for biomedical studies. However, the contemporary understanding of the principle of respect for autonomy has been largely influenced and shaped by the classic works of Kant (1785) and Mill (1859). In the following chapter, I will give a short overview of the basic definitions of autonomy given by Kant and Mill. Then, referring to the definition provided by Beauchamp & Childress (2009), I will show how a classical understanding of autonomy has been adopted in medical ethics, and how it can help us to frame the question of vulnerability.

Kant argued (1785) that respect for autonomy entails treatment of people as ends in themselves rather than as means. In his work on the metaphysics of morals, Kant (1785) provided the following definition for the principle of autonomy: "Not to choose otherwise than so that the maxims of one's choice are at the same time comprehended with it in the same volition as universal law." According to Kant, all autonomous agents have unconditional worth within themselves and can individually recognize their moral destiny. Therefore, a violation of autonomy means that a person has been treated merely as means in accordance with others' goals and beliefs.

Kant argued that people have rational powers and that this is the reason that motivates human beings to act morally. People are able to establish moral rules for themselves because of reason. However, the moral worth of an individual's actions does not depend exclusively on personal rules, but also on the moral acceptability of these individual rules on which an individual acts. According to Kant, the actions of individuals are autonomous only if they are based on the universal moral principles, which correspond to the categorical imperative. Kant formulated the categorical imperative as follows: "I ought never to conduct myself except so that I could also will that my maxim become a universal law" (Kant, 1785). It is important to acknowledge that Kant's theory of autonomy is exclusively focused on moral self-determination, while the principle of autonomy in medical ethics is generally about self-determination.

Mill was a hedonistic utilitarian, as he understands utility through the increase of happiness or pleasure. According to Mill, autonomy has an indissoluble connection with "individuality" of persons, he argued that "the cultivation of individuality... produces...well-developed human beings" (Mill, 1869, cited 2001: 59). An individual autonomous agent should act freely according to agent's personal mode of values, as long as they do not interfere with others' expressions of freedom and do not do any harm to others. In his work "On Liberty", Mill (1869, cited 2001: 63) stated the following: "If a person possesses any tolerable amount of common sense and experience, his own mode of laying out his existence is the best, not because it is the best in itself, but because it is his own mode". Although Mill (1869) argued that individuals should act according to their own beliefs, he also emphasized that society has to use its mechanisms of pressure and persuasion when individuals demonstrate inconsiderate or false beliefs.



Although the concepts of autonomy provided by Kant and Mill were of central importance to the formulation of ethical principles in biomedical research and care, they have number of limitations that have to be considered. According to Mill, persons should and can act according to their own ideals, even if these actions may harm them. For instance, a healthy individual may wish to participate in a clinical trial on hepatitis and, for this reason, may ask researchers to infect him with this virus. Although this person makes his own autonomous decision to be infected with hepatitis, it would be unethical for researchers to satisfy this request, because it may cause this person unnecessary harm or even death. In this hypothetical example of a biomedical study, the principle of autonomy, as defined by Mill, would conflict with the principle of non-maleficence that requires avoiding harm.

Kant's theory of autonomy has been the most influential for the formulation of the principle of respect for autonomous choices in medical ethics. However, this theory is limited when it comes to persons' motivations for participate in biomedical studies. According to Kant, only actions driven by moral duty can be seen as autonomous actions, while actions performed on the basis of emotions, such as sympathy or love, do not have equal moral worth. For instance, a healthy individual made a decision to participate in a clinical trial on cancer because his wife was diagnosed with leukemia. He made this decision based on the emotions of love to his wife and the desire to help. In this case, it can be said that the decision to participate in the clinical trial was based on emotions and therefore would not correspond to the Kantian theory of autonomy. Therefore, to justify the participation of individuals in biomedical studies, which are usually focused on the health of future generations, we should argue that such participation is driven by moral duty. This argument can be seen as a challenge. On the one hand, we could say that participation in biomedical research cannot be driven by moral duty, as such studies often use participants as means rather than ends in and of themselves. Thus, biomedical studies would not be justified by the Kantian theory. On the other hand, we can also argue that the current population has a moral duty to future generations to preserve the ecology of the planet, the environment, and also scientific knowledge. It could be said that through participation in biomedical studies, today's society fulfill their obligations to future generations. Following this argument, we can apply Kant's theory of autonomy to individuals' autonomous decisions to take part in biomedical research.

According to Kant, we cannot treat other individuals as means to our ends. That does not necessarily mean that Kant would not justify participation in biomedical research. What is important for Kant's notion of autonomy is that during research human participants are treated with respect and dignity as ends in themselves. There is, however, an important distinction between Kant's understanding of autonomy and the principle of autonomy that has been widely accepted in research ethics and will be discussed in the current thesis. It is important to acknowledge that Kant speaks about moral autonomy that is rooted in one's own moral reasoning. While in research ethics developed by Beauchamp & Childress (2009) and in the Belmont report that will be discussed later, principle of autonomy is associated with decisional autonomy that refers to the decision-making capacity of potential research subjects. Since this thesis is partially focusing on the definition of vulnerability stated in the Belmont report, I will follow the definition of decisional rather than moral autonomy.

Following the concepts of Kant and Mill, Beauchamp & Childress (2009) propose a practical definition of the principle of respect for autonomy, which can be applied in medical ethics. The authors state that for an action to be autonomous persons have to "act (1) intentionally, (2) with understanding and (3) without controlling influences that determine their action" (Beauchamp & Childress, 2009: 101). In the context of biomedical research, prospective subjects have the capacity to make autonomous decisions, if they are able to understand provided information, make judgments regarding this information in accordance with their own values, and are able to communicate their values and preferences with researchers. This definition of an autonomous person determines particular elements that have to be incorporated into the process of informed consent. These elements include:

- Disclosure. An initial intention and an idea of informed consent requires the disclosure of substantially relevant research information to patients. Patients will then be able to autonomously authorize their participation in a biomedical study. It is important to note that informed consent does not mean to provide full information about biomedical research, but rather to provide necessary, substantial information for patients to make their autonomous decisions. However, the provision of medical information does not simultaneously guarantees persons an understanding of this information.

- Understanding. Beauchamp & Childress (2009: 127) point out that “persons understand if they have acquired pertinent information and have relevant belief about the nature and consequences of their actions.” An understanding of pertinent information depends on the competence of a particular patient. Competence can be understood as “the ability to perform [a] task”, and the ability to judge acquired information. Therefore, for actions to be autonomous individuals have to express a substantial degree of understanding. However, understanding depends on a particular ability, whose criteria “vary from context to context” (Beauchamp & Childress, 2009: 112). For example, a refugee may be incompetent at making a decision about his participation in a biomedical study just after his arrival to a host country. This is because of the stress and uncertainty he may face in an asylum center. This does not mean that he will remain incompetent at making this decision after 2-3 years of living in a host country and getting used to its infrastructure and environment.
- Voluntariness is another very important feature of informed consent. An action is voluntary only if a person acts without being controlled by another person’s influences. An important factor must be emphasized here. Although it may seem that voluntariness is equal to autonomy, voluntariness only encompasses “the condition of control by other individuals” (Beauchamp & Childress, 2009: 132). In practice a person’s actions are neither purely voluntary, nor fully informed or autonomous, because of the cultural norms, beliefs, and social factors that influence a person’s decision-making. It does not, however, follow that a person’s actions are never adequately informed, voluntary, or autonomous.

According to Beauchamp & Childress (2009: 103), the principle of respect for autonomy “involves acknowledging the value and decision-making rights of persons and enabling them to act autonomously, whereas disrespect for autonomy involves attitudes and actions that ignore, insult, demean, or are inattentive to others’ rights of autonomous action.” Following Kant’s definition of autonomy, the authors explain that the principle of respect for autonomous decisions can be understood as both a positive and a negative obligation. As a negative obligation, a researcher has to respect the autonomous decisions expressed by participants and treat them with dignity. As a positive obligation, respect for autonomy implies that researchers have obligations to both treat participants with dignity and take actions in order to

encourage autonomous decision-making. However, Beauchamp & Childress (2009) are cautious in defining the principle of respect for autonomy as a positive obligation in the context of biomedical research. They emphasize that researchers should be careful in their attempts to foster autonomous decision-making, as these attempts can lead to a strong form of paternalism that may actually result in coercion and violation of an individual's autonomy. In addition, as Beauchamp & Childress (2009) emphasize, in order to foster someone's decision-making ability, researchers must be familiar with factors that influence one's decision-making. Such factors, however, may lay beyond the context of research or clinical care and thus researchers cannot know and do not have an obligation to know these nuances.

Although Beauchamp & Childress' (2009) definition of the principle of respect for autonomy has become a classic in medical and biomedical ethics, there is an important criticism to this concept. For instance, Hayry (2005: 31) argues that respect for autonomy, that he defines in accordance with Kant as an individual self-determination rooted in rationality, can restrict freedom, which he understands as "non-restriction of options". Therefore, Hayry (2005) suggests to shift from the respect for autonomy to respect for freedom that he sees as a more liberal concept. An important criticism has been provided by feminist scholars who have highlighted that principle of respect for autonomy established by Beauchamp & Childress "overemphasizes people's independence" (Ells, 2001: 218). Ells (2001) argues that Beauchamp and Childress apply their principle of autonomy to individuals whom they recognize as "fundamentally" equal, while ignoring their contextuality and interdependency. In addition, developments in social psychology emphasize the narrowness of this definition. A psychological approach insists on understanding the principle of respect for autonomy as a positive obligation. Proponents of this argument propose rethinking the principle of respect for autonomy with an emphasis on the social context of the autonomous agents. They also argue that researchers have an obligation "to enhance certain positive conditions that are likely to generate autonomous, or more autonomous reasoning" (Stoljar, 2008: 16).

According to a psychological concept of autonomy, medical researchers have to focus on the social contexts and physiological states of potential participants, and, if needed, they are obliged not only to respect the autonomy of individuals, but also to generate autonomous reasoning. Following this approach when constructing the process of informed consent, researchers have to take into consideration the social backgrounds of potential participants. For example, when conducting studies in rural

areas or involving illiterate populations, researchers must assure that they are able to communicate with participants using adequate terminology. This understanding of autonomy obligates researchers to be informed about the social and family situations of potential participants, and to be able to recognize whether these people belong to an oppressed group (e.g. race, class or gender). Therefore, researchers must be aware of the social, cultural, and family influences on participants' autonomy and must try to enhance individuals' ability for autonomous reasoning and decision-making.

On the one hand, the principle of respect for autonomy proposed by Beauchamp & Childress (2009) emphasizes that the ability of individuals to make autonomous decisions is one of the major ethical principles in biomedical research. According to these authors, while researchers have to respect an individual's autonomy, they do not have an obligation to strengthen the ability of a person to make autonomous decisions. Therefore, the authors understand the principle of respect for autonomy as a negative, rather than as a positive obligation. On the other hand, the psychological approach aims to expand researchers' obligations towards respect for a person's autonomy, by taking into consideration the complex social and psychological conditions of each individual. Although the psychological approach aims to understand the principle of autonomy as a positive obligation, it does not provide a solution to the concern about hard paternalism. How far should researchers go to enhance participants' ability to make autonomous decisions? What kind of guidelines should exist to define social conditions that may influence persons' decision-making? How can researchers, who themselves live within a particular social framework, identify and judge social influences on other human beings?

In conclusion, beginning with a classical understanding, the concept of autonomy in medical ethics has been shaped by different developments in ethics and social sciences. In order to make the definition of autonomy more applicable to the current complexities of biomedical studies, Beauchamp & Childress (2009) argue for the adequate autonomy of research participants. This autonomy should entail that potential subjects have a sufficient understanding and ability to make decisions regarding their participation in research. Vulnerability in this context would mean a jeopardized ability of potential research subjects to exercise an adequate level of autonomy due to coercion by or the influences of other individuals. Although the psychological approach suggests that researchers should take actions to enhance

participants' ability to make autonomous decisions, it does not suggest a possible methodology or guideline that researchers should follow to take these actions.

The concept of vulnerability as the jeopardized ability of autonomous decision-making has been adopted by most of the ethical guidelines for biomedical studies involving human subjects, including the Belmont Report. In the next chapter, I will demonstrate how the contemporary definition of autonomy and the subsequent definition of vulnerability developed by Beauchamp & Childress (2009) were translated and adopted in the Belmont Report. I will show the possibilities and limitations of the Belmont Report with relation to research involving vulnerable populations. In addition, I will propose a way to develop the proposition of the psychological approach, in order to enhance persons' ability to act autonomously without arriving at hard paternalism.

## Chapter 2. Concept of vulnerability in research ethics

The ethical framework of research involving human subjects has been determined by several ethical guidelines, established at different times in reaction to particular events in the history of clinical trials. The first of these guidelines was the Nuremberg Code established in 1947 in order to protect people participating in research. This code was a reaction to the horrifying experiments that were conducted by Nazis during the Second World War. Although the Nuremberg Code was an important stage in the development of research ethics, it was not significant enough to prevent several infamous trials, such as the Tuskegee Study<sup>1</sup> or the hepatitis trial with mentally disabled children (Robinson & Unruh, 2008). The next step in the development of research ethics was the creation of the Declaration of Helsinki in 1964. The Declaration established strict requirements for informed consent in research involving human subject and focused on the protection of individuals. These developments provided an important foundation for the establishment of the Belmont Report in 1978. This was the first document that formulated the three ethical principles that are currently used in medical ethics: respect for persons, beneficence, and justice (Miracle, 2016).

The Belmont Report was developed in the US by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The context in which this document was developed is of great importance. The Tuskegee Study was one of the most blatant and controversial medical trials of that time. As a consequence, one of the main concerns of the National Commission was to protect individual participants from possible coercion in research. The central focus of the commission was on the autonomy of persons. In addition, they had the particular task of distinguishing clinical practices from research practices, in order to avoid a therapeutic misconception that might eventually lead to exploitation. Three ethical principles were developed to allow the ethical performance of biomedical research. It is important that the Belmont Report is not a philosophical paper that aimed to contribute to the discussion of ethical principles. Instead, as noted by Joneson, one

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<sup>1</sup> 'In 1932, the Public Health Service, working with the Tuskegee Institute, began a study to record the natural history of syphilis in hopes of justifying treatment programs for blacks. It was called the "Tuskegee Study of Untreated Syphilis in the Negro Male". The study initially involved 600 black men – 399 with syphilis, 201 who did not have the disease. The study was conducted without the benefit of patients' informed consent. Researchers told the men they were being treated for "bad blood," a local term used to describe several ailments, including syphilis, anemia, and fatigue. In truth, they did not receive the proper treatment needed to cure their illness. In exchange for taking part in the study, the men received free medical exams, free meals, and burial insurance. Although originally projected to last 6 months, the study actually went on for 40 years' (Center for Disease, Control and Prevention, 2015).

of the report's developers, "it was a proclamation that had to ring true in the ears of scientists, policymakers, politicians, ethicists, journalists, and judges" (Jonsen, 2005: 5).

Interestingly, Beauchamp, one of the authors previously mentioned, played a major role in the development of the Belmont Report. He was invited as a staff philosopher to write the "Belmont Paper" and to develop its three ethical principles at the same time as he was writing his book with Childress. Therefore, as he himself noted, these two papers co-influenced each other (Beauchamp, 2005). However, Beauchamp (2005: 15) cautiously notes that the book with Childress is philosophically grounded, while the principles established in the Belmont Report are largely associated with "our cultural tradition" and are rooted in "common morality". He emphasizes that the report and the book have "substantially different moral visions" (Beauchamp, 2005: 15). In particular, the principle of autonomy in the Belmont Report is mixed with a principle of protection for non-autonomous individuals. Additionally, the Belmont Report does not distinguish between the principles of non-maleficence and beneficence, while Beauchamp & Childress (2009) emphasize the importance of this separation. Nevertheless, this interesting coincidence may help us to better understand the basis for the development of the Belmont Report.

Although the Belmont Report is not a philosophical paper, but rather practice-oriented, the report aims to shape the process of biomedical research in order to protect research subjects from possible harms they may experience during research. Therefore, in this thesis I will discuss the Belmont Report as an important document that creates an ethical framework for biomedical studies involving human subjects. It obliges researchers to provide all of the significant information to potential participants in order to obtain voluntary informed consent and avoid coercion and exploitation. Another important feature of the Belmont Report, and the reason why I discuss this particular document, is that it was the first document that used and discussed the concept of vulnerability in the context of biomedical research.

The report characterizes vulnerable people as those who:

- (1) Lack the capacity to give voluntary informed consent;
- (2) Have a high possibility of being exploited in research;
- (3) Have increased risk of being harmed through the research process (Rogers et al., 2012).



According to this document, vulnerable groups include, but are not restricted to, “racial minorities, the economically disadvantaged, the very sick, and the institutionalized,” whose “dependent status and their frequently compromised capacity for free consent” require particular protection when these groups are involved in research (National Commission for the Protection of Human Subjects of Biome Beha Resea, & Ryan, 1978).

Although the Belmont Report was a significant stage in the development of research ethics, its concept of vulnerability has a number of limitations. Based on the presence or absence of the aforementioned characteristics, the Belmont Report determines population groups as vulnerable or not, a method of defining vulnerability that has been called “labeling” (Luna, 2009). The practice of labeling presupposes that there are fixed and presumed conditions (e.g. an ability to provide informed consent) that a population group has to fulfill to be recognized as vulnerable or non-vulnerable, yet disregards possible differences within this group.

The practice of labeling in research ethics has been criticized by various scholars for being both too narrow and too broad in its application of the concept of vulnerability. It is too narrow because it defines vulnerable populations largely based on people’s ability to give voluntary informed consent. Therefore, the protection of vulnerable populations can be achieved through improving the process of informed consent. Rogers et al. (2012: 15) explain, however, that “if this is not possible [to improve the process of informed consent], participants deemed vulnerable are excluded from research altogether.” Based on this assumption, many population groups, such as children, the mentally ill, and the socially and economically disadvantaged (such as refugees) may be excluded from biomedical research and from the benefits these studies may bring to their health and wellbeing.

Other scholars, such as Hurst (2008), Levine et al. (2004), and Luna (2009) emphasize that the practice of labeling used in the Belmont Report is too broad in its application of vulnerability. As was noted above, a population group is recognized as vulnerable if it meets certain conditions, such as an inability to give voluntary informed consent, or a high possibility of being harmed in the research process. However, this definition of vulnerability may be applied to almost any research participant. For example, elderly people may have a higher risk of harm in biomedical research because of their age; students may be recognized as lacking the ability to give voluntary informed consent because of their economic dependency. As Levine et al. (2004: 46) rightly noted, however, if everyone is

vulnerable then the concept of vulnerability no longer has force. Therefore, it loses its capacity to protect those who are actually vulnerable and require protection.

In addition, Nickel (2006) demonstrates a contradiction in the principles that the Belmont Report establishes in order to protect vulnerable populations. The principle of respect for autonomy entails that research participants be treated as autonomous individuals and that their participation in research be determined by their capacity to provide voluntary informed consent. If a person has difficulty providing informed consent then researchers have an obligation to ensure special protection for this person and to establish required safeguards. For example, if a research participant is a child then informed consent has to be obtained through the child's official surrogates. In this context, "vulnerable populations are those whose capacity to safeguard their own interests, by autonomously giving (or refusing) informed consent, is compromised" (Nickel, 2006: 247).

Another principle is fairness or justice, which is expressed in the Belmont Report (1978) as follows:

[T]he selection of research subjects needs to be scrutinized in order to determine whether some classes (e.g., welfare patients, particular racial and ethnic minorities, or persons confined to institutions) are being systematically selected simply because of their easy availability, their compromised position, or their manipulability, rather than for reasons directly related to the problem being studied.

This definition means that it would be unjust to involve individuals who are already burdened by society and for whom the benefits of this research would not outweigh the additional harms that this study may impose on them in biomedical research. Following this definition of justice, Nickel (2006: 248) points out that vulnerable people would be those who:

[I]n the absence of protections, would be more likely to take on the burdens of participation in research in virtue of some feature they share as a group, where this is not compensated by other suitably related benefits that accrue to the group.

However, these two principles give rise to a contradiction of paternalistic attitudes in the Belmont Report. Specifically, as the Belmont Report tries to protect vulnerable populations in biomedical research, it simultaneously contributes to their exclusion from research and thus from the benefits of participation in a study. Nickel (2006: 248) expresses this argument in the following:

Just as it is bad to target a badly off group because of its vulnerability, it is also bad to avoid a group completely. When some group is avoided, it thereby fails to receive, as a whole, a benefit that might otherwise accrue to it, while comparable benefits are accruing to others.

Therefore, the concept of vulnerability presented in the Belmont Report has several complexities that arise when applying this concept in practice.

- First, the concept of vulnerability may be seen as too narrow, as it reduces the notion of vulnerability to a specific aspect of some population groups, while ignoring the possible features of research that may be harmful for some research participants.
- Second, the concept of vulnerability may be understood as too broad as it labels a large number of population groups as intrinsically vulnerable without taking into account different research contexts that may make the same people vulnerable in one context and non-vulnerable in another.
- Third, the definitions of vulnerability presented in the Belmont Report contradict each other in that they require protection for vulnerable populations, while also depriving them of the rights of participation in biomedical research.

The Belmont Report was the first document that applied the concept of vulnerability to biomedical research. However, more recent and influential ethical guidelines for biomedical research have also used this concept. For instance, the edited version of the Declaration of Helsinki (2013) has two references to vulnerability. One is regarding the special protection of vulnerable populations, and the second is regarding the possible benefits and harms that research may impose on its participants. Referring to vulnerable populations, The Declaration of Helsinki describes them as those who “may have an increased likelihood of being wronged or of incurring additional harm” (World Medical Association, 2013: 4).

Another ethical guideline for biomedical research involving human subjects was developed by the Council for International Organizations of Medical Sciences (CIOMS). It provides a more comprehensive definition of vulnerability:

“Vulnerability” refers to a substantial incapacity to protect one’s own interests owing to such impediments as lack of capability to give informed consent, lack of alternative means of obtaining medical care or other expensive necessities, or being a junior or subordinate member of a hierarchical group. Accordingly, special provision must be made for the protection of the rights and welfare of vulnerable persons (CIOMS, 2002: 18).

One specific feature of the aforementioned guidelines, including the Belmont Report, is that they understand vulnerability as an embodied characteristic of a social group. This makes vulnerability an unavoidable and intrinsic condition of a particular population group, such as pregnant women, children, elderly people, and refugees, without differentiating between different socio-political, environmental, and thus research contexts.

However, labeling a whole population group as vulnerable in order to protect this group can actually bring about more harm than benefit. One of the classic examples

of such harms is the exclusion of women from participating in biomedical research because of their “pregnable” bodies, as expressed by Merton (1994). In order to protect women and their future children and to avoid possible harm to women and potential (or current) fetuses that may be caused by research, women and pregnant women have been intentionally excluded from participation in biomedical studies. This problem only gained serious attention in the late 1990s. This exclusion as a form of protection has resulted in a lack of important medical knowledge regarding women’s health, and the lack of important medications for women and pregnant women, as most studies have been conducted on men. Therefore, all of the medical information and medications derived from these studies were based on men’s anatomy.

Similar to the exclusion of women from biomedical research, we currently face the exclusion of refugees and asylum seekers in biomedical research, once again for the sake of their protection. In his article, Gifford (2013) describes his experience of communicating with an ethical committee that makes decisions regarding ethics in biomedical research based on the aforementioned guidelines. Gifford and his colleagues received a rejection from this ethical committee for their pilot project with refugee youth. The main objection was regarding the questions that the researchers were planning to use to investigate the best application of scaled items - “How much do you like ice cream?” and “Given a choice between ice cream and pizza, which would you chose first?” The ethics committee objected that references to food might provoke re-traumatization of refugee youth who had experienced starvation.

The HREC [Human Research Ethics Committee] judged these questions as having the potential to cause harm to resettled refugee youth because they were refugee. The logic was that being refugees, these youths would have experienced starvation and like other forms of trauma, questions about food were seen as a risk to re-traumatise (Gifford, 2013: 42).

After meeting with this committee and explaining to them that “although all of the youth had a refugee past, they also were like other teenagers who enjoyed sweets and ‘junk’ food”, Gifford and colleagues received approval for their study (Gifford, 2013: 42). In this case, the ethics committee perceived refugee youth as a group, characterized by conditions of suffering, pain, starvation and other miseries that may be associated with forced migration, while ignoring their non-refugee experience as less important. As we can see from this example, one of the complexities that may arise in biomedical research involving refugees is that refugees may be associated with the concept of suffering; they are understood by ethical guidelines and thus by ethical committee as intrinsically vulnerable. This understanding of refugees as intrinsically vulnerable because of their belonging to a group of forced migrants may

silence people's experiences of the ordinary lives that they had before migration, and thus their capacity for making autonomous decisions on their behalf.

Despite possible complexities with inclusion of refugees in biomedical studies, research, as was highlighted in the introduction, may be seen as an important instrument to advocate for refugees' health issues. For example, research on antimicrobial resistance (AMR) can have two possible outcomes. First, refugee populations can have the same or lower level of antimicrobial resistance compared to the local population. These data can promote the de-stigmatization of refugees as a dangerous group that spreads diseases, an image that is often exploited by radical political parties. Similar results have already been obtained in the Netherlands after the screening of Syrian refugees for tuberculosis (TB). The results of the screening showed that incoming Syrian refugees have the same level of TB as the local population in the Netherlands. As a result of this study, Syrian refugees do not go through obligatory TB screenings when they arrive to the Netherlands (National Institute for Public Health and the Environment, 2016). The second possible outcome of AMR research is that refugees may have higher levels of antimicrobial resistance than the local population. These data can affect the practice guidelines for medical practitioners by correcting the treatment procedures that are usually used for particular medical conditions, as this treatment would not be effective for refugees who may have resistant genes. Therefore, research can improve the quality of provided health care for refugees, by taking into account their unique conditions.

This chapter scrutinized the concept of vulnerability as it is presented in the official guidelines for biomedical research involving human subjects, with a specific focus on the Belmont Report. I looked at the labeling and often contradictory nature of the concept of vulnerability presented in the report. I then mapped possible difficulties in the application of the concept. It is important to note that I do not deny the importance of the Belmont Report and I do not propose abandoning it. The focus of this thesis is the concept of vulnerability in research ethics. In the following chapters, I will propose a way to rethink this concept in order to enrich the Belmont Report and to benefit potentially vulnerable refugees as research subjects. In the next chapter, I will focus on an in-depth critique of the labeling concept of vulnerability and propose a rethinking of the concept in order to make it more sensitive to research contexts.

### **Chapter 3. Rethinking vulnerability as a context-dependent concept**

The labeling application of vulnerability has been widely criticized by different scholars who propose a re-evaluation of this concept in a context-dependent, flexible, and participatory way. In this chapter, I will follow the arguments of the following scholars: Luna (2009), Lange et al. (2013), and Hurst (2008). These authors provide the most flexible approach to vulnerability in biomedical research. They combine the requirements of the Belmont Report for both an autonomy driven process of informed consent and protection of research subjects with a more context-sensitive definition of vulnerability. This flexibility in defining vulnerability would allow us to incorporate practices of participation into the process of research and to contribute to the enhancement of participants' autonomy. In addition, based on this context-sensitive definition of vulnerability, I will propose a solution to the critique of the psychological approach discussed in the first chapter.

Luna (2009) proposes the idea of "layers of vulnerability," which implies a relational analysis between a person and the circumstances s/he lives in. The author argues that depending on the research situation and research protocol that reflect the social and political contexts of a study, the same population groups may be exposed to different vulnerabilities. For example, a Sudanese refugee living in a camp in a rural area of Nigeria has very different layers of vulnerability than a Sudanese refugee living in a camp in Germany. Therefore, these two people, although they both belong to a refugee group, live in different environments and, therefore, are exposed to different vulnerabilities. While a refugee in Nigeria may have very limited access to food and clean water, a refugee in Germany almost never encounters these problems. Thus, different safeguards are needed if refugee research is performed in Nigeria or in Germany, as refugees living in these countries face different vulnerabilities. Luna (2009: 123) emphasizes that "not everybody is alike", therefore, it would be too simplistic to rely on the labeling practices of defining vulnerable populations. There is a need for a different approach, which would ensure that vulnerability is acknowledged in research and vulnerable populations are protected.

However, the concept of layers of vulnerability also has some limitations. In particular, it will be a task for researchers to define these layers and establish particular safeguards to protect vulnerable individuals. In the same way as research

subjects, researchers also live in particular contexts and think using certain definitions. Depending on the angle from which researchers look at the research participants and the contexts they live in, participants' layers of vulnerability may vary. For example, in our study of AMR, microbiologists expressed a clear public health orientation in biomedical research involving refugees. Therefore, the angle from which they judged the vulnerability of refugees was initially determined by public health discourse. These microbiologists determined that the aim of AMR research is to explore and decrease possible risks for public health. They argued that results from AMR research can benefit health care practices by providing evidence regarding mechanisms of antimicrobial resistance and risk factors that influence acquisition of AMR. One of the microbiologists explained,

It is useful to have some background information about the risk levels within our community, or within our region. ... If we find that MRSA [resistant bacteria] is high in refugees that would necessitate hospitals to deal with them in the same way as with people who spent some time abroad or who were admitted to a hospital in a foreign country – isolate them, screen them, and treat them if necessary (Microbiologists, group interview).

Following this argument, microbiologists did not see that the study itself could harm refugees in certain ways. Therefore, they did not perceive refugees as vulnerable in this particular study. The microbiologists expressed the necessity of involving healthy refugees in AMR research, because it would benefit public health. At the same time, they noticed some difficulties that could arise from the political discourse surrounding this group of people. One of our participants emphasized that stigmas surrounding refugees already existed, constructed and supported by political discourse. Therefore, if we perform biomedical research involving refugees, we will have to deal with political stigma anyway.

It is societal and political stigma, which is the problem, and not microbiological stigma of the research. I understand that every activity can increase a risk, but it is really the political stigma that is the underlying problem. The study and the publicity around this study merely 'uncovers' the stigma that is already there (Scientist, 63).

Interestingly, the only layer of vulnerability that microbiologists defined was the stigmatized political position of refugees. They did not consider risks related to therapeutic misconceptions, or to refugees' (mis)understanding of the concept of antimicrobial resistance, as well as possible mistrust by refugees of researchers as representatives of a host country.

Another example may be the position of nurses, their way of looking at refugees, and their possible participation in biomedical studies. Nurses' perspectives on biomedical research can be seen through a person-oriented approach. An important difference is that nurses, in contrast to microbiologists, take a clinical care

perspective and thus focus on the interests of actual research participants, and not merely on the possible benefits for future generations.

In the study on antimicrobial resistance in Maastricht, I conducted a group interview with two public health nurses who have experience of both working as practicing nurses and working with public health programs. One of the characteristics of antimicrobial resistance research on healthy individuals is that it does not provide any individual results, as these results cannot benefit or harm research participants. This research has a strictly public health orientation and aims to develop practical guidelines in accordance with the explored microbiota that is “the ecological community of commensal, symbiotic, and pathogenic microorganisms that literally share our body space” (Lederberg, 2001). However, because this type of research does not have any personal benefits for participants, nurses were strictly against the screening of healthy individuals.

The population is not ill at the refugee center; there is no need to do screening. It [antimicrobial resistance] does not do anything with healthy people. ... If you test them at a refugee center, what would you do? You can't do anything with this knowledge, you can't treat them (Public health nurses, group interview).

Different angles of judging a research study may produce different layers of vulnerability for research participants. Depending on those who make the decision about the layers of vulnerability of potential participants, these layers may be different. Therefore, although the concept of layers seems attractive for its flexibility, this constitutes the risk of focusing on one vulnerability while ignoring others, depending on the perspective the researchers will follow.

A similar concept has been developed by Lange et al. (2013) who argue that vulnerability has three major sources: inherent, situational, and pathogenic.

- Inherent sources of vulnerability are a nearly inevitable characteristic of all humans as needy and dependent beings. This is similar to embodied, unavoidable vulnerability.
- Situational sources determine specific contexts that make people vulnerable to something at a particular time or place. For example, a surgeon working in a clinic in Estonia in 2016 is not vulnerable to being killed by a bombing, while the same surgeon working in a clinic in Aleppo, Syria, in 2016 is vulnerable to such an incident.
- Pathogenic sources of vulnerability arise from “dysfunctional personal or social relationships” (Lange et al., 2013: 336). This implies different situations of abuse, prejudices, or political injustices and violence. Also,



pathogenic vulnerabilities include situations that were described above regarding the position of women in biomedical research, when particular paternalistic prejudices towards women exclude them from the possible benefits of biomedical research.

The authors do not propose a particular definition of vulnerability, but they define three sources that aim to sensitize different aspects of vulnerability. According to Lange et al. (2013), researchers have an obligation to ensure that research does not exacerbate or create new vulnerabilities among people involved in a study. The sources of vulnerabilities proposed by these authors serve as an instrument for researchers to recognize vulnerabilities and to protect potential participants, if needed. Interestingly, along with Luna, the scholars Lange et al. (2013) depart from labeling practices in defining vulnerable populations in biomedical research and emphasize the importance of the research design and the responsibilities of investigators in defining vulnerabilities in each particular research context.

In line with these concepts of vulnerability, Hurst (2008) proposes a shift from the focus on population groups as carriers of vulnerability to a focus on research contexts and study designs that can impose or exacerbate vulnerability. In biomedical studies, Hurst (2008) argues, it is important to know what vulnerabilities the process of research can impose on potential participants rather than the intrinsic vulnerabilities of participants themselves. She defines vulnerability as “an identifiably increased likelihood of additional greater wrong” that may be imposed on a population through the research process (Hurst, 2008: 195). This definition does not imply vulnerability as an embodied characteristic of a particular group, but rather it requires conditional analyses of whether some particular research (e.g. research protocol, methodology) threatens a particular population group, and whether this group requires additional protection. Hurst reformulated the question about vulnerability from “What is vulnerability?” to “What makes people vulnerable?” For instance, when conducting a biomedical study, part of its process is to obtain written informed consent from potential participants. In research focusing on women’s health, it is general practice that researchers obtain consent directly from a woman. However, if this study is conducted in Afghanistan, for example, researchers may impose a particular level of risk on a woman, if they ask her for consent, while avoiding asking for permission from her surrogates, which could be a husband, brother, or father. While it may seem to be unethical to ask for consent for a competent adult from her surrogates, this practice may be rooted in the culture

of a particular community. Negation of this culture may harm a research participant. Therefore, more flexible and context-dependent research methodology is needed. In this context, the question of vulnerability may be further re-formulated as the following: What aspects of the research design may exacerbate or create vulnerability among a particular population group?

For my analysis of refugee research, I will follow the critique provided by Hurst (2008) and Luna (2009), referring to vulnerability as a conditional and contextual notion rather than an embodied characteristic of a group. I agree with the aforementioned authors that we should reformulate the question of vulnerability and explore the nuances of research processes and designs that may make people vulnerable. As noted by Lange et al. (2013), researchers have responsibilities to identify vulnerability and avoid it wherever possible, while increasing the autonomy of research participants. However, the critique that was provided for the concept of layers of vulnerability is also applicable to these two concepts. The aforementioned authors propose a re-configuration of the concept of vulnerability in a more flexible and context-dependent manner. They propose focusing on the potential of a research design to create vulnerability, rather than on the intrinsic vulnerabilities of individuals. The actors who are supposed to make judgments about research designs are investigators, who, as was demonstrated with the examples of the microbiologists and nurses, themselves may have different ideas about vulnerabilities and express different perspectives when looking at research processes.

An important actor that may help to overcome this complexity is ethical committees that have to assess and judge research designs. Ethical committees act as safeguards, have to objectively determine the vulnerabilities of potential participants, and decide whether a particular research design is appropriate for the inclusion of these participants. However, ethical committees rarely have enough resources to conduct proper investigations regarding the opinions of different actors in research, which may also be time-consuming. Therefore, I propose to integrate elements of a participatory approach in the process of designing and performing biomedical research itself. Participation means that we integrate different angles together to judge vulnerability, including the experiences and expectations of the people who are exposed to these vulnerabilities.

In general, the voices of refugees in different studies are represented by others, including either researchers, UN agencies and NGO representatives, or

governments of host countries. Another alternative is that refugees' voices are not represented at all and therefore refugees' issues are not acknowledged in a political and social agenda.

For example, in the study of antimicrobial resistance, some refugees were positive about biomedical research and expressed their willingness to participate in such studies. However, only one out of six refugees could distinguish the practices of research from clinical care. Another five people mixed these two practices, demonstrating a therapeutic misconception. One of the refugees explained, "It [research] would be helpful for me, I can take care about myself. If there is something bad with me, researcher will tell me" (Ammar, 28).

Refugees justify biomedical research, however they do it based on clinical care ethics, implying that research will benefit their personal health. One of the refugee participants explained his willingness to participate in AMR research by his perception of research as a preventive measure for his own health.

If person has something wrong they [researchers] try to fix it, they are trying to make him better.  
... Research is for the person. They will do research to know what medicine is good for the person.  
... If someone has something not good they will try to get him better, to get him in a hospital, it [research] is better for us (Modar, 24).

On the one hand, it is possible to argue that the therapeutic misconception demonstrated by refugees is an important obstacle to receiving informed consent and to conducting biomedical research involving these populations. On the other hand, this misunderstanding may be seen as a kind of moral claim about the incorporation of values and meanings of refugees into a larger body of a research design that would acknowledge their claim for care within the research.

In the previous chapter, I examined how the concept of vulnerability is presented in the Belmont Report. Aiming to protect potentially vulnerable population groups, often through their exclusion from a research, the Belmont Report creates a space for a hard paternalism that presupposes that researchers, physicians or ethics committee take actions and make decisions on the behalf of patients or research participants "without their participation" (Pellegrino & Thomasma, 1987: 25). In this chapter, I analyzed three theories that suggest a shift from paternalistic labeling concept of vulnerability to a more sensitive and participatory concept. However, these theories have their own limitations and constitute a risk to accumulate a lot of power on the hands of researchers. In the next chapter, I will propose a participatory approach as a possible research design that allows for dialogue between different participants and helps to create a contextual framework of vulnerability constructed through the expectations of different research actors. Through participation, while

pursuing larger public health goals, researchers involve participants in dialogue about their individual issues and worries.

## **Chapter 4. Participatory approach: working through vulnerability beyond the Belmont Report**

Participatory approach has been widely adopted in studies in the fields of anthropology and ethnography as a methodology for learning about peoples' experiences and stories through their own words and meanings. In this chapter, I will propose an adaptation of participatory approach as a methodology for biomedical research involving refugees. This methodology will help to contextualize the issue of vulnerability while avoiding hard paternalism and at the same time empowering refugees by granting them more autonomy in the decision-making regarding their participation in research.

Participatory research is a methodology that is based on "reflection, data collection, and action that aims to improve health and reduce health inequalities through involving people who, in turn, take action to improve their own health" (Baum et al., 2006). There are a number of principles that characterize participatory methodology. Although these principles were developed by the International HIV/AIDS alliance (2006) to work with HIV positive people, they can be adapted in order to work with vulnerable groups in general:

- The principle of participation identifies the right of all people to actively participate and influence decisions that can affect their lives;
- Empowerment is the process of increasing the influence and capacity of persons to decide on their own behalf and to perform actions they think will be the best for them;
- The principle of collaboration refers to the idea of coproduction of knowledge in order to understand a problem and find a common solution to solve it;
- Use of different visual and verbal techniques can allow people with different backgrounds to participate equally in complex analysis and learning;
- Inclusion of people who are usually silent in the decision-making process.

In the subsection 4.1., I will demonstrate how the participatory approach was originally applied in anthropology and I will then highlight how it can enrich biomedical studies involving refugees.

The subsection 4.2. is devoted to the analysis of the learning health system as an example of the combination of research and care in practice. The participatory approach may be a helpful instrument when working with potentially vulnerable groups, because this approach shifts the researcher-subject relationship to a softer

doctor-patient relationship. However, this shift raises another important question that was sensitive in the Belmont Report, the separation of research and care. On the one hand, an association of research and care can benefit research participants who usually do not receive clear health benefits when taking part in biomedical studies that focus on the health of future patients. On the other hand, this merger may fuel a problem associated with therapeutic misconception that can eventually lead to the exploitation of research participants. The learning health system was adopted in the US and is focused on combining research practices and care within hospitals. Working with the experience of this system, I will show how a participatory approach can help to narrow the gap between clinical care and public health ethics, while decreasing therapeutic misconception.

#### **4.1. Participatory methodology in anthropological research**

Two of the fields where participatory approach plays a significant role are anthropology and ethnography. Anthropologists use participation to gain an in-depth understanding of the local community that they are studying. Lassiter (2005: 16) developed an approach of collaborative<sup>2</sup> ethnography and defines it as “an approach to ethnography that *deliberately* and *explicitly* [emphasis in original] emphasizes collaboration at every point in the ethnographic process, without veiling it—from project conceptualization, to fieldwork, and, especially, through the writing process.” A distinctive feature of anthropology and ethnography is that participation starts from the initial stages of research. A researcher can come to a community without any preliminary research questions or theoretical frameworks. Anthropologists work in collaboration with populations to identify research problems and questions that they will study and analyze together.

In one of his works, Lassiter (2008: 71) points out that participatory action research “plants roots in locality, and assembles cooperative cocitizenships and coactivisms built on the counderstandings emergent in the collaborative research partnerships between and among anthropologists and local publics”. The process of knowledge production in collaborative ethnography has a very flexible nature. Rather than one-sided interpretations by researchers, knowledge in participatory research is a result of collaboration between researchers and local participants. This approach can provide an opportunity to gain an in-depth understanding of a community’s problems and meanings through the insights of this community.

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<sup>2</sup> For the purpose of this thesis terms collaborative and participatory used as synonyms

Working with local meanings, anthropologists aim to understand essential health problems in the way they are perceived in a community. For example, doing participatory-action research in HIV/AIDS among young men in the industrial area of India, the Deepak Charitable Trust found that:

AIDS itself was not perceived as a major problem by the young men in this area. Instead, men who were engaging in high-risk behaviors wanted to find sex partners at least partly to avoid “thinning of the semen” and sexual dysfunction and fatigue, which were believed to be long-term consequences of masturbation and nocturnal emissions (Minkler, 2005: ii6).

Therefore, local understandings can redirect the focus of a research study and illuminate local complexities that would otherwise be ignored or simply unknown in a non-participatory study.

It is accepted in anthropology that lay knowledge and traditions can govern the research process. Negotiations of different and often diverse attitudes and agendas are an important challenge in collaborative ethnography. It is obvious that outsider-researcher and insider-laypersons can have different standpoints regarding research objectives. In cases when it is impossible to come to a common decision, anthropologists can emphasize the distinction in opinions, as this is also an important result for a collaborative study. For instance, describing the study “I Was Content and Not Content: The Story of Linda Lord and the Closing of Penobscot Poultry”, the ethnographer Alicia Rouverol (2003) points out the disagreement that appears during her dialogues with the participant. Rouverol emphasizes this disagreement in order to illustrate a dynamic of collaboration with the participant, and to show that common meanings are not always in place in participatory research.

Our key area of disagreement . . . was in the question of what businesses owe communities when they shut down. I believe that some sort of restitution is in order when long-time businesses close and leave a community that is significantly dependent on that industry for its livelihood. Linda believes that businesses do not necessarily owe a community anything when they leave. We chose to include in the book’s edited interviews our exchange on this point, to draw attention to our differing perspectives (Rouverol, 2003: 66-67).

The process of negotiation that can result in an unresolvable disagreement is still a successful result that emphasizes the deep distinction between outsider and insider understandings of the same problem. Working in participation with research subjects, investigators have to acknowledge participants’ attitudes towards a particular problem, but they also have to express their own attitudes and disagreements.

In her work, Rouverol (2003) raises the important question of “shared authority” in collaborative research. Neither researchers nor participants are on the “top” of the research process, but they co-influence and co-shape each

other's attitudes, as was the case with Rouverol's study. Rouverol (2003: 67) points out that "Her [Linda's] stance toward plant closure, its effects on workers, and the government's responsibility, had become more critical, strident even, since Steve and Cedric's interviews with her five years earlier. And this shift seemed important to include". Therefore, not only researchers can change their attitudes through the process of participation, but also participants can re-think their understandings of some problems.

An important distinction and one of the unique features of participatory action research is its spiral structure. In anthropology, researchers collaborate with participants at all levels of research, including the analysis of interviews and writing of reports. This structure provides a possibility for an in-depth understanding of local attitudes, and involves participants as active collaborators who both share and analyze information.

Participatory methodology has been widely accepted by anthropologists who study health issues in different communities. This approach gives an opportunity for participants to express their own worries and beliefs during the research process, and also helps researchers acquire detailed knowledge through continuous communication. Such a methodology would be particularly helpful in working with vulnerable population groups. Through participation in research, human subjects can exercise their autonomy, which would not be limited to the process of informed consent, but rather expanded to the whole research process. The expansion of the principle of respect for autonomy plays a significant role in the next subsection. In the following section, I will focus on the learning health system, which aims to blur the boundaries between researcher-subject and doctor-patient relationships. This example will help us to understand how we can incorporate participatory methodology into a process of biomedical research, while decreasing possible therapeutic misconceptions.

#### **4.2. Learning health system: merging research with care**

The period between the production of new healthcare technology and its implementation often takes up to 17 years (Budrionis & Bellika, 2016). As a result, patients receive care that was established 20 years ago and often do not have access to newly developed techniques and treatments. The learning healthcare system (LHS) aims to narrow this gap and thus bring a laboratory to the consultancy room and vice versa. In this system, science may learn directly from practice and



practice may apply new scientific knowledge in a shorter period. The learning health system is:

designed to generate and apply the best evidence for the collaborative healthcare choices of each patient and provider; to drive the process of discovery as a natural outgrowth of patient care; and to ensure innovation, quality, safety, and value in health care (Olsen et al., 2007: ix).

The learning health system offers doctors the double position of practitioner and researcher at the same time. Simultaneously, it transforms patients into potential research subjects. For example, a patient that has a gastric ulcer receives an established standard treatment for this medical condition in a hospital. A physician may offer this patient to participate in a study in a hospital to test an alternative treatment method that might be better than the standard one, although there is no evidence of this yet. If the patient agrees, they would simultaneously be in two dimensions of care and research, while still being within the same facility. LHS has three major aims (Budrionis & Bellika, 2016):

1. To quicken the process of implementation of produced knowledge in clinical practice;
2. To enhance a culture of shared responsibility;
3. To engage doctors and patients with the processes of evidence production and implementation.

A distinctive feature of the learning healthcare system is its incorporation of clinical research within routine clinical practice. Although LHS aims to blur the line between research and care, some authors, such as Kelley et al (2015), emphasize the centrality of physician-patient relationships and shared decision making principles. As LHS presupposes the inclusion of research practices into care, however, the question of informed consent becomes an important issue. The learning health system does not just substitute researcher-subject relationships with doctor-patient ones, but conjoin them. This aspect of LHS is crucial for an understanding of the participatory approach in biomedical studies, as the question is how to blur the line between research and care, while still maintaining a distinction between these two practices.

Shared decision-making (SDM) is central to the learning health system. It is a process of collaboration between patients and their physicians regarding the process of treatment, or patients' participation in research within clinical settings (Barry & Edgman-Levitan, 2012). SDM means the exchange of valuable information between a patient and a physician. Physicians have to share available information about treatment options, or possible benefits and harms that research may cause a

patient. In response, patients have to be open about their values, attitudes, and preferences about research and care. Therefore, a patient and a physician together can come to a common decision about treatment trajectories, or about the necessity of participation in a particular biomedical study. Through shared decision-making, therapeutic and research practices become more transparent and flexible. Patients can negotiate and correct their treatment together with physicians, thus sharing the responsibility of such decisions (Barry & Edgman-Levitan, 2012). Kelley et al (2015: 13) argue that SDM facilitates collaboration between patients and physicians by bridging “the power gap between patient and physician knowledge while promoting transparency and trust,” which is essential to the learning health system.

Guiding the process of decision-making through collaborations between patients and their physicians, SDM provokes an ethical challenge in healthcare practices, the shift from an evidence-based to a values-based practice (Williamson, 2014). This is a transformation of therapeutic decisions from evidence and scientific centered to individual and person-centered. This transformation is essential, especially in certain spheres of clinical practice, such as prenatal screening, discontinuation of active treatment toward the end of life, or the use of hormone replacement therapy. Patients transformed from silent recipients of doctors’ decisions to active players in the decision-making process.

Although the ideas of the learning healthcare system seem attractive in that they can empower patients and give them direct access to the results of clinical trials, implementation of this system brings up the important questions of autonomy and trust. These questions are decisive cornerstones in shared decision making, as physicians make an offer of research participation based on the information patients provide to them. In addition, patients make their autonomous decisions based on the information provided to them by physicians. On the one hand, collaboration facilitates shared decision making and provides a possibility for both patients and practitioners to exercise their autonomy. On the other hand, uncritical trust can also provoke a number of risks for both patients and physicians. Referring to Emanuel & Emanuel (1992), Williamson (2014) argues that in healthcare practice it is almost impossible to grant full autonomy to patients, as they may lack important medical and biological knowledge. Thus their decisions would still require expert assistance:

When it is understood as independence, autonomy has little normative content to help people work through difficult issues. It suggests people should be allowed to choose freely, but provides no assistance on what they should or ought to best select—that is, the view that autonomy amounts to noninterference or “self-understanding . . . excludes evaluative judgment of the patient’s values or attempts to persuade the patient to adopt other values” (Williamson, 2014: 9).

Autonomy implies non-interference. Thus a clinician has to accept an autonomous patient's decision without judging this decision or persuading the patient to change it. In practice, however, patients rarely experience independent autonomy, as their decisions are usually influenced by the recommendations and judgments of doctors they trust. In their research about patient perspectives of the learning healthcare system, Kelley et al (2015) show the centrality of trusting patient-physician relationships in making decisions about participation in research.

Patients identified trust as a core value that motivated their views on how research risk should be managed, suggesting that perceptions of minimal risk might vary depending on the trusting nature of the physician–patient relationships. ... from the patients' perspective trust is a way to navigate risk, it is only a successful strategy when trusted persons or institutions uphold expectations and are trustworthy (Kelley et al, 2015:12).

However, the uncritical trust patients may grant their physicians can provoke a risk of violating a patient's autonomy and persuasion in decision-making. Indeed, if the researcher and the physician are the same person, it would be difficult for a patient to separate them. It may become problematic to separate their advice regarding treatment trajectories and research participation. Shared decision making is only possible through collaboration and trust between patients and their physicians. On the one hand, shared decision-making has the capacity to expand patients' autonomy, allowing them to influence the treatment process. On the other hand, it creates a risk of violating this autonomy through the notion of uncritical trust.

In addition, although the learning health system presupposes that patients and practitioners are equal collaborators in the process of decision-making, it is almost impossible for this to happen in practice. The physician always occupies the position of an expert who has a special education and experience, and who patients are used to trusting regarding their health. Examples from anthropology show us that researchers and participants can become equal partners through the process of research. However, long-term collaborative relationships between patients and physicians only strength the inequality of their positions. A physician is a person who possesses expert medical knowledge, experience, and the legal position of an expert. This important distinction once again emphasizes the possible risks of coercion and exploitation that may appear in trusting relationships in the learning healthcare system. In the next chapter, I will demonstrate how we can address the issue of trust within the context of biomedical research involving refugees.

In this section, I introduced two different fields where the principles of the participatory approach and collaboration are applied. Anthropology proposes full cooperation with participants at all stages of research. Shared decision-making is a

process of involving patients as active participants in decision-making regarding their treatment or participation in research in the learning health system. These areas of knowledge present different ways of applying the participatory approach. Learning from these two fields, in the next chapter, I will define the possibilities and limitations that participatory methodology can offer biomedical research involving vulnerable populations, particularly refugees.

## **Chapter 5. Participatory action research: possibilities and limitations**

After a general description of the participatory approach provided in the previous chapter, chapter five will scrutinize how the participatory approach can be adapted for biomedical studies involving refugees. I will show how this approach can on the one hand empower refugees and enhance their autonomy, but on the other hand, I will also highlight a weakness of this approach that may lead to the exploitation of research participants due to their uncritical trust to researchers.

Participatory methodology aims to empower research participants, or patients in the case of the learning health system, and to engage them in the process of decision-making. Because of these aims, participatory methodology is an appealing tool for scholars working with vulnerable populations. For example, Holkup et al (2004) adapt the participatory approach in their study with a Native American Community. Another scholar, Veale (2005), proposes participation in research with children. In addition, participatory methodology has been widely adopted by scholars working with refugee populations. For instance, Marlowe (2009; 2013) applied the participatory approach in his study of the traumatic experiences of Sudanese refugees in New Zealand. I will rely on this example to demonstrate the limits and benefits that the participatory approach can offer biomedical studies involving refugees.

Marlowe (2009; 2013) conducted a three-year research project that included in-depth narratives with 24 Sudanese men and an ethnographic engagement with their community. He performed participatory action research in order to build communication and trust with people who experienced forced migration. He wanted to understand refugees' experiences and values in their own terms.

Every communication consists of a minimum of two people, a speaker and a listener. As Marlowe notes, however, this translation of information becomes more complex when the discussion is loaded with social, historical, cultural, and political gaps between the speaker and the listener. Refugee populations are a very sensitive subject for research, as they represent both local cultural norms and traditions, and the experience of trauma associated with forced migrations. To build communication with these people, a researcher has to understand their cultural background.

The traditional methods of conducting interviews with the use of a questioner and limited communication with respondents, do not always allow for a deep

understanding of what is said by people from different cultures. Therefore, the translation of meaning from a participant to a researcher may not be clear, and results obtained by these studies can be insufficient or even wrong in their representations of participants. Marlowe emphasizes that the life experiences of refugees are often characterized by the notion of trauma and threat, which can lead to two problems with traditional interview methods.

1. Respondents can feel fear or shame in telling the truthful story of their lives, or they can distrust researchers. Therefore, it may lead to a risk of insufficient or even incorrect information, if respondents do not feel comfortable enough to disclose their actual stories.
2. Refugees may report only the traumatic experiences of forced migration, while denying other stories from their lives that could emphasize very different notions of what this person actually values and thinks. Although many refugees have painful experiences regarding their migration, it would be incorrect to narrow a person only to this background, while denying other stories and parts of their lives.

Thus, when doing research with refugees, it is essentially important “to meet these people on their terms in both time and place rather than from territory of the often more powerful positions and perspectives that we command and enjoy” (Marlowe, 2009: 45). Marlowe articulates that researchers have to “play an integral role in elevating people’s voices in a collaborative manner that acknowledges who these people are and importantly, who they want to be” (Marlowe, 2009: 46).

A traumatic experience in itself is not a specific characteristic of refugee populations. Traumatic experiences can also be relevant to other vulnerable groups of people, such as people infected with HIV. However, I would argue that studies involving refugees are inherently different from those involving other vulnerable population groups. When studying vulnerable groups of people within one community, researchers do not actually move to completely different normative and cultural contexts. For example, if we perform research involving women from our society who experienced domestic violence, we will not delve into a completely new cultural framework with its own meanings and symbols. Although these women are vulnerable, they exist within the same social discourse as we do, and we can communicate with them using mutually understandable terminology. The unique feature of refugees and migrants in general, is that they bring one context within another. If we perform research involving refugees, we cannot rely on the

terminology that is accepted in our society. Instead we have to construct a new one that will be understood by both refugees and researchers. The responsibility of investigators in refugee research is to translate and mitigate two different contexts that exist in one place with researchers from a host country and refugees from another country.

Marlowe proposes that researchers should actively engage with the studied community and involve the community in active participation in the research. In his article, he refers to the term “slowly slowly” that was widely used by his respondents (Marlowe, 2013). This expression, “slowly slowly,” may serve as a good representation of the core principles of participatory action research. Participatory studies develop in a spiraling way during which the researcher, in collaboration with refugees, gradually determines the “authentic backstage responses” and local knowledge (Marlowe, 2009: 45). Doing participatory action research means recognizing that “people are experts of their own lives and that it is necessary to understand people beyond the problems they are encountering” (Marlowe, 2013: 157). This understanding can be done through collaborative work with people whose stories we study.

The benefits of participatory action research can extend beyond the framework of the research itself. To illustrate this point I will rely on the example of the participation effect from a water project in an expanded program of immunization (EPI) (Eng et al., 1990). During their project, Eng et al test the following hypothesis:

Communities which participate in decision-making throughout all phases of a water supply project [project took place in villages in Togo and Indonesia] will display higher rates of participation in other primary health care activities such as EPI than communities which have either a non-participatory water supply project or no water supply project at all (Eng et al., 1990: 1350).

Interestingly, this hypothesis was statistically proven. Based on the data on diphtheria, pertussis, and tetanus (DPT) immunization series, Eng et al concluded that villages that were part of a participatory water supply project had approximately 10% higher DPT series completion rates than villages with non-participatory project groups and in control groups where no water supply project took place.

Participatory action research can bring benefits not only within the framework of the research, but can also expand its influence throughout time. Therefore, this research has a capacity to empower research participants from a long-term perspective. Through participation in research as active players, community members are shaped and influenced by this research and learn how to take active positions and express their own thoughts and beliefs.

Although the participatory approach is an appealing instrument, it has a number of limitations that have to be considered carefully. The first limitation is rooted in contextuality. Although researchers should obtain inside cultural knowledge and implement it into the research process, it may be problematic to do so in some situations. In particular, certain local cultural and religious principles possessed by participants can be recognized as unethical and thus cannot be fulfilled. For example, in some cultures women are not treated as equal to men. This does not mean, however, that in a study, women's voices should be less valid than that of men. In addition, in the case of refugees, people come from distinct cultural and legal frameworks. Therefore, some traditional principles that may be valuable for refugees can be illegal in host countries.

Second, participatory approach raises an important question of critical trust between participants and researchers. As it was discussed in the previous chapter, collaborative research in anthropology, as well as shared decision-making within the learning health system, require trusting relationships between actors. The participatory approach implies continuous communication between researchers and participants that supposed to combine benefits of clinical care and public health ethics. This combination leads to the merging of roles of the researcher and the doctor. However, the doctor-patient relationship are rather paternalistic and require that patients grant a sufficient amount of trust on their physicians. At the same time, the researcher-subject relationship is inherently different in nature and require critical judgements of researchers by subjects. On the one hand, it is possible to suggest that the aim of the participatory approach is to build trusting communication between researchers and participants and, therefore, this trust will protect participants from possible exploitation. On the other hand, as O'Neill (2002: 18) rightly noticed it, the suggestion that trust will protect research subjects is naïve.

Participation can be seen as a form of beneficence as it contributes to the enhancement of refugees' autonomy in making decisions regarding their participation in biomedical studies (Pellegrino & Thomasma, 1987). Autonomy is a precondition of trust, therefore the process of communication in the participatory approach has to be devoted to the enhancement of autonomy in order to build critical trust that is different from blind trust. Therefore, when we speak about trust in biomedical research, it is a "reflective" and "self-confident" trust (Solomon & Flores, 2003). This kind of authentic trust is different from blind trust by its recognition of possibilities for disillusion and its caution for possible treachery. Solomon & Flores



(2003: 92) define authentic trust as “trust that is well aware of the risks, dangers, and liabilities of trust, but maintains the self-confidence to trust nevertheless.” Another author, O’Neill (2002: 193), emphasizes that the notion of trust implies “risk taking”; people have to put their trust in researchers or caretakers “without guarantees”.

The building of authentic trust is based, as was highlighted by Sutrop (2007), on information. Indeed, in order to make an autonomous decision and to put trust in researchers or institutions that fund a particular study, or to a government that supports it, an individual needs a sufficient amount of information about these actors and research itself. As was noted by the same author, the foundation for blind trust is a “lack of information and critical thinking” (Sutrop, 2007: 196). Therefore, authentic trust has to be rooted in information and critical reflection on this information.

However, it would be premature to conclude that the provision of sufficient information is enough to build trusting relationships between researchers and research participants. In her book on autonomy and trust, O’Neill (2002: 25) emphasizes that “trust is most readily placed in others whom we can rely on to take our interests into account, to fulfil their roles, to keep their parts in bargains”. This argument consist of two very important points. First, trust is associated with both information about research, and also with information about the competence of those who are performing a given study. This point was also highlighted by Sutrop (2007: 192), who argued that in order to put their trust in someone, individuals have “to believe that another will be able to do” her work professionally. Second, in order to take part in a study and to build trusting communication with researchers, people have to believe that researchers will take their interests seriously. This point is of great importance. The provision of information that is usually a part of the process of informed consent does not grant the creation of participants’ trust in researchers, if they, an institution they represent, or a government in general are not trusted by the population.

In their work, Solomon & Flores (2003: 92) argue that “in authentic trust it is the relationship itself that is the focus of attention.” This is the relationship between different actors involved in the process of research, including potential participants, researchers, nurses, institutions, and government bodies. If there were no trust between certain of these actors, it would be very difficult to involve participants in a study. For example, when I conducted an ethnographic study in an asylum center

in Maastricht, refugees were willing to talk with me and be interviewed by me, although I was not part of the medical team conducting AMR screenings and I am not Dutch. Not that many people, however, were willing to give their stool samples for microbiological analysis. Although all of the samples were anonymized, many refugees expressed concern that the results of microbiological tests could influence their status as refugees and that they may not receive a residence permit. I think that this concern was rooted in the deep distrust that refugees have in host countries in general, and in researchers as their representatives in particular.

The provision of sufficient information in biomedical study is not enough for the creation of trusting relationships between researchers and participants. As was emphasized by O'Neill (2002), there is a need for trustworthy institutions that support and conduct biomedical studies. I would also add that another requirement for the building of trust is time. The expression "slowly slowly," which appeared in the research conducted by Marlowe (2013), can serve as a good example of this requirement. In order to build trust with research participants, who may be skeptical about the whole institution conducting the study, researchers have to spend a sufficient amount of time developing authentic trust among participants. This notion of time will be further discussed in the next subsection where I will propose a way to rethink the methodology of biomedical research in order to make it more flexible and responsive in refugee research. Participatory methodology can be helpful here.

In this section, I demonstrated the way that the participatory approach can be applied to vulnerable populations and in particular to refugees. To be able to grasp and understand local beliefs, researchers have to involve refugees in research as partners and collaborators. Although participatory research may require a significant amount of time, it can bring additional benefits to both participants and researchers. One of the biggest obstacles in applying the participatory approach to biomedical studies is the limits of trust. On the one hand, trusting communication can introduce significant benefits. On the other hand, it can provoke a risk of exploitation of potentially vulnerable population. In the following subsection, I propose a design for biomedical research involving refugees that will address the complexities associated with the vulnerability of refugees, trusting communication, and risks of exploitation.

## **5.1. Participatory methodology for biomedical research involving refugees**

The perception of research subjects as experts on their own lives has the potential capacity to enrich research processes with insights, meanings, and experiences. In particular, laypersons' knowledge can help an investigator to better understand how to properly and ethically perform a study involving vulnerable populations, such as refugees. For example, if a study focuses on the processes of HIV dissemination among people living in a refugee camp, investigators have to know what these people understand as a sexual contact (e.g. in some cultures it is believed that anal sex is not sexual contact, and thus some people may not report that they have these practices). In order to acquire truthful reports from people, researchers have to know local understandings about sexual contact and HIV. In order to obtain this knowledge, they must first establish trusting communication.

In the previous subsection, it was demonstrated that building trusting communication within the framework of biomedical research could be a challenging issue. Inclusion of refugees adds an additional constraint, as, due to their increased vulnerability, refugees may distrust any official representative of a host country, including investigators. Based on the principles of participatory methodology, I will propose a two-layer design for conducting biomedical studies involving refugees. This methodology will allow us to contextualize the possible vulnerabilities of refugees, enhance their autonomous reasoning, and avoid possible therapeutic misconceptions. The first layer can be understood as a broadening of the process of informed consent. It aims to construct trusting communication between researchers and participants, and to develop an appropriate methodology and tools for the second layer. The second layer is the performance of the biomedical study, which includes collection of biomedical materials. Each of the layers has to be separately approved by an ethics committee. After the first stage is concluded, researchers have to prove to the ethics committee that they fulfill their obligations and spent a sufficient amount of time with potential subjects that allowed building of an authentic trust. The second layer has to be based on the results obtained during the first phase. Let us describe this scheme in more detail.

The first layer represents the core of the participatory methodology. It can be seen as a separate ethnographic study that has two major aims:

1. The introduction of researchers and their interests to potential participants and vice versa. During this introduction, researchers have to state that their research interests are different from care, and have to discuss possible vulnerabilities that may appear in the biomedical study.
2. The development of research methodology and acceptable forms of informed consent for a future biomedical study that will involve the same population group.

This study has to gain separate approval from an ethics committee. In this phase, researchers have to take on the role of ethnographers who have come to an unknown culture and have to understand its norms and traditions. During this time, researchers have to learn how to speak about particular issues, such as antimicrobial resistance for example, with these people, and have to build authentic trust with them. This part may be particularly challenging. There are, however, some helpful tools used in anthropology, which were discussed above. For example, researchers may invite participants to laboratories and introduce them to some basic algorithms they use at work. The most important part here is transparency. If researchers wish to build trusting communication and learn about individuals' practices and beliefs, they have to let participants learn the same things about the researchers.

It is clear that not all potential participants are interested in laboratory work or scientific goals. However, there are always some people who are sincerely curious about these things. These people should be actively involved in this first phase of research, as they may help to gain inside knowledge about the community. In addition, they could provide support for the study by gaining the trust of other members of a population group. Through the process of building trusting relationships, researchers, in collaboration with participants, have to develop adequate tools for the second stage of the study. In particular, they have to create an appropriate form of informed consent that could be understood by members of a population group, and develop other practical and behavioral rules for performing their biomedical study. Even such detail as, for example, wearing a white coat may be of a great importance in some communities. In our study with Syrian refugees, all the participants stated that they would never trust a medical researcher if he is not wearing a doctor's white coat. This small detail may be an important element in the success of the whole study.

The second layer represents the conducting of a biomedical study, and has to receive separate justification from an ethics committee. Although this scheme may be time consuming, it can benefit both researchers and participants. The separation of a study into two different layers involves a particular sensitivity to potential, and possibly vulnerable, research participants. It gives a sense of respect to participants and may enhance their autonomous reasoning through active participation in the research process. It may also benefit researchers in that they can obtain more truthful and coherent data. In addition, although the first stage may be time consuming, the second phase of the study may be performed much faster and more smoothly. Indeed, if all of the methodology is already developed and researchers have already established contacts with potential participants, the biomedical aspects of a study can be performed in a short period.

Conducting research involving refugees that are potentially vulnerable and often do not trust any representatives of a host country maybe a serious challenge for researchers. However, exclusion of this population group from biomedical studies can cause more harm as to the health of these people as to the public health of the community. Indeed, the lack of medical or biological knowledge about some population group may cause harms not only to these individuals but also to public health, as in the case of contagious diseases. This two-layered participatory methodology may help to alleviate some difficulties associated with the vulnerability of refugees. The process of building trust and the co-creation of a research methodology may help researchers to include refugees in biomedical study, while not creating or exacerbating their vulnerabilities. In addition, researchers will not gain too much power, as they will always have to prove to the ethics committee that they actually spent enough time with potential research participants. This approach understands the principle of respect for autonomy as a positive obligation and involves research participants in an active dialogue with researchers. At the same time, the first layer of such a methodology preserves a sufficient amount of time to define and discuss the possible vulnerabilities of participants with different research actors.

## Conclusion

At the beginning of this thesis, I argued that there is a need for re-configuring the concept of vulnerability as it is currently presented in ethical guidelines for biomedical research involving human subjects. The focus of my argument was a particular group that is usually recognized as vulnerable, refugees. Working with the classic notions of autonomy and jeopardized autonomy (i.e. vulnerability), I analyzed how this concept has been translated into research ethics and implemented in ethical guidelines, in particular in the Belmont Report.

The way that the Belmont Report utilizes the concept of vulnerability has been called “labeling”. This means that the concept of vulnerability serves as a label that can be attached to different population groups. The practice of “labeling” has been widely criticized for its inflexibility and ignorance of contextual nuances that may surround different members of population groups. I referred to three groups of authors, Hurst (2008), Lange et al. (2013), and Luna (2009), in order to demonstrate several possible ways of rethinking “labeling” the concept of vulnerability in a more flexible way. However, these three concepts have a common problem; the definition of vulnerability in each of them depends on those who have a voice in the research (e.g. researchers, funding organization, nurses). Therefore, if researchers do not perceive refugees as vulnerable, they may not include necessary safeguards to protect these participants. In order to overcome this problem, I propose the implementation of a participatory methodology in the process of biomedical studies.

The participatory approach aims to empower research participants. By applying this approach to biomedical studies and incorporating personal issues into public health research, we may enhance people’s understanding of health as a public phenomenon, as well as give them an opportunity to raise their individual health issues. Therefore, participation helps one to see and treat people beyond their perceived status as vulnerable individuals. This participatory structure can allow for the following benefits:

- Through communication with potential participants, the researcher will be able to design a context-sensitive research program that will avoid the creation or exacerbation of vulnerabilities;
- The empowerment of refugees through dialogue with researchers;
- The incorporation of personal benefits, such as consultations with medical specialists, into biomedical research that is pursuing public health goals.

It has been demonstrated, however, that despite the definitive benefits that a participatory approach can offer to biomedical research involving refugees, this approach has some limitations. One such limitation is contained in the notion of trust between participants and researchers that may lead to the exploitation of human participants. In order to settle this problem, I offered a two-layered design for a biomedical study that can be seen as two separate studies. The first layer is devoted to the process of building trust and shaping communication, after the conclusion of this phase researchers will have to provide an evidence for ethics committee that they fulfill their obligations of trust building. During this stage, researchers, in collaboration with participants, have to develop forms of informed consent and appropriate tools for the second phase of research, which is the biomedical study itself. This design will allow researchers to solve problems related to mistrust and therapeutic misconceptions, as they involve refugees in a collaborative dialogue. In addition, such a methodology can help researchers to map possible vulnerabilities faced by refugees, while at the same time contributing to an empowerment of refugees who can raise their voices and make autonomous decisions. Although, the proposed approach can be time-consuming, I do not argue that it should become a universal standard for conducting biomedical research. However, the participatory approach is a helpful methodology to conduct biomedical studies in particular contexts, specifically with vulnerable population groups.

## Summary

The concept of vulnerability in biomedical research that involves refugees is of a contradictory nature. On the one hand, ethical guidelines, such as the Belmont Report, establish that refugees belong to a vulnerable population and require additional protection. On the other hand, the application of such guidelines in practice often leads to hard paternalism and an overall exclusion of refugees from biomedical studies and their possible benefits. In this thesis, I conducted a critical analysis of the concept of vulnerability in research ethics and proposed an approach to rethinking this concept in a more flexible way. I propose the implementation of participatory methodology, which is characterized by the inclusion of all research actors into a process of research development and performance, into the design of biomedical studies. I suggested that biomedical research with refugees should include two layers, or separate studies. First, biomedical research should include an ethnographic enquiry into the cultural meanings and values of a refugee group. During this stage, researchers have to build trust and communication with participants and develop responsive tools for the second stage of research, which is the biomedical study. This type of research design will allow for the respectful treatment of refugees and in-depth analyses of possible vulnerabilities that may be imposed by biomedical studies.

Title in Estonian: Haavatavuse mõiste ümbermõtestamine: põgenike kaasamine biomeditsiinilisse uurimustöösse



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